

Dear Representative \_\_\_\_\_:

As an independent laboratory performing genetic and molecular diagnostic testing, we urge you to cosponsor H.R. 1699, the *Patient Access to Critical Lab Tests Act of 2009* introduced on March 25, 2009, by Congressmen Jason Altmire, Anna Eshoo and Tim Murphy. This legislation will help ensure that patients have timely access to cutting edge genetic and molecular diagnostic tests and give doctors the tools they need to make smarter, more effective, safer, and more personalized decisions for their patients.

Advancements in laboratory medicine have enabled providers to be far more effective in targeting treatment for patients or in determining a patient's predisposition to a disease or condition. Many of these tests are not only helping to save lives but also substantial money in the delivery of care. The testing performed by our laboratory (*describe test(s) and value.*)

However, our ability to continue to be able to provide these tests and any incentive to develop new tests is threatened as an unintended consequence of an arcane Medicare billing rule. Under current regulations, the date of service for a laboratory test ordered less than 14 days after a patient's discharge from a hospital is the date on which the specimen was collected. The effect of this rule is to treat a lab test ordered after the patient is discharged from the hospital (up to 14 days after discharge) as if the test were actually performed while the patient was *in* or *at* the hospital. The result is that the hospital must take on professional and financial responsibility for a test ordered and performed outside the hospital after the hospital stay—frequently when the hospital has no relationship with the laboratory performing the test and even when the hospital has no relationship with the physician ordering the test. Hospitals have not been willing to take on this role.

The practical effect of these rules is that patient access to these tests has been impacted. These rules create obstacles and unnecessary delays for Medicare beneficiaries to receive these innovative, personalized medicine tests. There is no policy rationale for forcing hospitals to assume a middleman role with these tests; it is an unintended consequence of the date-of-service rule. Although the rule operates reasonably in most circumstances, it does not for a relatively small number of important tests. This legislation will allow independent laboratories offering complex diagnostic laboratory tests to bill Medicare directly without forcing the hospital into a middleman role it does not wish to perform.

Please cosponsor H.R. 1699 which will better ensure Medicare beneficiary access to innovative, personalized medicine diagnostic tests like those we perform.